

REMARKS

Claims 1-40 are rejected. Claims 6, 11, 15, 20, 25, 27, 30 and 37 are amended. Claims 9, 16, 18, 19, 21, 23, 24, 26, 28, 29, 31, and 32 are canceled without prejudice.

The amendments are fully supported in the application as filed and contain no new matter, at least at page 4, lines 1-13. page 5, lines 4-16 and original claims.

OATH/DECLARATION, AFFIDAVIT/DECLARATION

The marking on the signature line of each of the above documents as filed is the applicant's signature. Therefore, the documents are not defective because they are signed.

DOUBLE PATENTING

Claims 1-40 are provisionally rejected for obvious-type double patenting over claims 1-3 and 6-13 of co-pending application No. 11/105,756 in view of Wong.

Applicant respectfully disagrees, at least because instant claims 1-10 require a sustained release matrix; claims 11-14 require specific administration methods not including fixing a device to the sclera; claims 15-24 recite a method of enhancing post-surgical ocular moisture; claims 27-36 are composition claims reciting specific doses; claims 37-40 are method claims reciting specific concentration of agents. These are patentable distinctions, and applicant respectfully asserts the rejection is overcome and requests its withdrawal because the Examiner's Action does not reference the distinctions as

previously set forth. Should the Examiner disagree, applicant requests deferral of a response pending allowable claims.

CLAIM REJECTIONS UNDER 35 U.S.C. §102

Claims 1-4 are rejected under 35 U.S.C. §102(e) as anticipated by Robinson. Applicant respectfully disagrees.

Robinson discloses a drug delivery device. The device must be specifically fabricated to provide agent via single or dual mode release kinetics during a single treatment regimen. In contrast, claims 1-4 recite a treatment method using rapamycin and/or ascomycin to treat an ocular condition. Robinson does not anticipate applicant's method of treatment, at least because applicant's method provides sustained release of an effective amount of rapamycin or ascomycin.

Robinson's device is either a matrix implant or a reservoir implant. A matrix implant requires two polymers: (1) a bioerodible solid matrix structure polymer that is permeable to a therapeutic agent, and (2) a water-soluble polymer having greater water solubility than (1) (column 5, lines 16-29). A reservoir implant requires a silicone-encapsulated reservoir containing the therapeutic agent, an inner core within a nondegradable polymeric layer, and an attachment means (column 7, lines 31-56). Use requires a threshold determination of whether the device is to be single or dual mode, and then loading the implant with agent and then providing the implant. The matrix contains 1-50 wt% of agent. In applicant's method, a matrix contains 3-5 mg of

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rapamycin and/or ascomycin; this is an amount and the agent is not formulated at a percentage of the matrix.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

Claims 5-19, 25-29 and 33-36 are rejected under 35 U.S.C. §103(a) as obvious over Robinson in view of Kulkarni. Applicant respectfully disagrees.

Robinson is distinguished as analyzed above. Additionally, applicant disagrees with the Examiner's characterization of Robinson's drug quantity; it is 1-50% wt of the composite material. Applicant's method claims recite a concentration of agent. Further, with respect to claims 11-14, and 25-26, these are limited to specific injected administrations, not an implantable device. With respect to claims 15-19, these recited methods for enhancing post-surgical ocular moisture, while Kulkarni discloses the use of rapamycin for the treatment of ocular inflammation. There is no disclosure of use of rapamycin to enhance ocular moisture, post-surgical or otherwise.

Kulkarni discloses, in connection with topical administration but not ocular topical administration, a rapamycin concentration of 0.1 – 5%, preferably 2% (column 8, lines 4-7). There is also disclosure of an appropriate daily dose of 0.01-50 mg/kg (column 8, lines 11-14). However, there is no disclosure of a suitable concentration for anything other than topical administration and there is no disclosure of ocular topical administration. The claims are amended to recite topical administration at a concentration from 50 pg/ml to less than 1 µg/ml (i.e., less than 0.0001%) or injection at a dose in the range to about 200 µg/ml (i.e.,

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0.02%). The maximum concentrations distinguish Kulkarni, because it discloses a concentration range of 0.1-5%.

Claims 20-24, 30-32 and 37-40 are rejected under 35 U.S.C. §103(a) as obvious over Robinson in view of Ueno. Applicant respectfully disagrees for the reasons set forth below.

Robinson is distinguished as analyzed above. Ueno discloses treatment of dry eye using a macrolide including rapamycin derivatives. Ueno discloses that macrolides that can be administered "systemically or locally by oral administration, intravenous administration (inclusive of transfusion), subcutaneous administration, rectal or vaginal administration [sic], administration to local site in the eye (inclusive of eye ointment)" (column 8, lines 27-36). Ueno's dose, when administered systemically, is about 0.0001-1000 mg, and when administered locally the composition is applied to the eye and contains the active ingredient in a proportion of 0.001-10.0 w/v%. Thus, Ueno discloses topical administration at a concentration range of 0.001-10.0 w/v%. There is no disclosure of any other form of local administration, nor of any concentration for any such other form of local administration (column 8, lines 41-48), nor intraocular injection or implantation.

Thus, applicant asserts Robinson in view of Ueno does not render claims 20-24, 30-32, and 37-40 obvious, and applicant respectfully requests this rejection be withdrawn.

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CONCLUSION

Based on the foregoing, applicant believes the application is now in condition for allowance. Applicant does not believe there is any fee due with this submission. Should any fees or surcharges be deemed necessary, the Examiner has authorization to charge fees or credit any overpayment to Deposit Account No. 23-3000. The Examiner is invited to telephone applicant's undersigned representative with any questions or issues.

Respectfully submitted,
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